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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,530	01/29/2004	Henrich Cheng	L0735.70003US00	2231

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EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
03/30/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,530	CHENG, HENRICH	
	Examiner	Art Unit	
	MICHAEL G. MENDOZA	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 35-38 been renumbered 34-37 respectively.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-21 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer et al. in view of Cheng et al. 62335041.

5. Aebischer et al. teaches a method of repairing a nerve root avulsion in a living vertebrate, the method comprising: bringing a first avulsed end and a second avulsed end close to each other without an intermediate graft, and applying to the gap between the first and second avulsed ends a fibrin glue mixture so that the fibrin glue mixture is

simultaneously in contact with the two avulsed ends to form an attachment between the avulsed ends, wherein the first avulsed end is in the peripheral or central nervous system and the second avulsed end is in the peripheral nervous system. It should be noted that Aebischer et al. fails to specifically teach wherein the fibrin glue mixtures only active agents consists of a growth factor, fibrinogen, aprotinin, and divalent calcium ions. However, it is well known in the art that fibrin glue can be made from a calcium chloride solution reconstituting freeze-dried thrombin combined with an aprotinin solution reconstituting fibrinogen. The combination of thrombin with fibrinogen making fibrin. It is also known to add growth factors to the combination.

6. Cheng et al. teaches a method for repairing an avulsion comprising applying a fibrin glue mixture consisting of a growth factor, fibrinogen, aprotinin, and divalent calcium ions as the only active agents (see entire document). Therefore, it would have been obvious to modify the method of Aebischer et al. in view of Cheng et al. to apply a fibrin glue such that of Cheng et al. because the fibrin-based tissue glues do not impair nerve fiber growth (col. 8, lines 17-19).

7. Aebischer/Cheng teaches the method of claim 1, wherein the growth factors are selected from the group consisting of a glial cell line-derived neurotrophic factor, transforming growth factor-beta, fibroblast growth factor, platelet-derived growth factor, and epidermal growth factor, vascular endothelial growth factor, and neurotrophin (col. 5, lines 66-67); wherein the components of the fibrin glue mixture can be applied to the gap simultaneously or separately; wherein the growth factor is fibroblast growth factor, which is acidic or basic fibroblast growth factor, wherein the divalent calcium ions are

provided by the addition of calcium chloride or calcium carbonate (col. 6, lines 12-14); wherein the fibrin glue mixture consists of acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride; further comprising suturing or anatomizing the first and second avulsed ends.

8. As to claim 10, Cheng et al. teaches a vial B with 1 ml of aprotinin solution with 1000 KIU bovine lung aprotinin. This solution is mixed with vial D containing 2.5 ml of calcium chloride solution. Bringing the total volume of the solution of B + D to 3.5 ml. Added to the solution of C + D, dry fibrinogen between 115-232 mg in a vial A and dry thrombin between 4.9-11.1 mg in a vial C, to bring the total volume above 3.5 ml. For ease of calculation the examiner will use the solution volume of 3.5 ml. The solution of 3.5 ml with a total of 1000 KIU of aprotinin in the solution would equate to approximately 286 KIU/ml of solution. Therefore, Cheng et al. reads on the limitation of the fibrin glue mixture consists 0.0001-1000 mg/ml of fibroblast growth factor, 10-1000 mg/ml of fibrinogen, 10-500. KIU/ml of aprotinin and 1-100 mM of calcium chloride.

9. As to claim 11, Cheng et al. teach a mixture consists acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, lines 1-16). It should be noted that fails to specifically disclose 1 mg/ml of fibroblast growth factor, 100 mg/ml of fibrinogen, 200 KIU/ml of aprotinin, and 8mM of calcium chloride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 UPSQ 215 (CCPA 1980).

10. As to claims 2, 12-21, 37 and 38, Aebischer/Cheng teaches and all of the limitations except for, wherein the first avulsed end is in the peripheral nervous system and the second avulsed end is in the central nervous system at a nerve root or more specifically the cervical root and the spinal cord. An avulsion is the tearing away of a body part accidentally or surgically. As recited in the claims, the nerves needing repair comprise ends. The method of Aebischer et al. is for repairing severed nerves by combining nerve ends of the severed nerve. If a separation occurs at the site as recited in the claim, the method of Aebischer et al. is fully capable of repairing the avulsed nerves by combining the ends.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734
March 27, 2011